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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,735	09/26/2003	Eric B. Kmiec	NaPro-2 CON	8506

7590 05/05/2006

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EXAMINER	
BAUSCH, SARAE L	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/672,735	KMIEC ET AL.	
	Examiner	Art Unit	
	Sarae Bausch	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) *6 and 36-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/05, 7/04, 2/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to papers filed 02/15/2006.

Election/Restrictions

2. Applicant's election with traverse of claims 1-5 and 7-35 in the reply filed on 02/15/2006 is acknowledged. The traversal is on the ground(s) that a thorough search of group I produces the nucleic acid molecules set forth in the claims of group II and the subject matter is sufficiently small and closely related as to be capable of examination together. This is not found persuasive because the search for nucleic acids is not coextensive with a search for a method of producing a stabilized double D loop at a target sequence requiring searching different classes/subclasses for example searching both group I and II would require the use of different electronic resources with different search terms and queries. Furthermore, the requirement for restriction is that the inventions must be independent or distinct and there would be serious burden on the examiner if restriction is not required. In the instant case, each group is in a separate classification (group I is classified in 435/6 and group II is classified in 536/23.1), each group is separate subject matter (group I, methods of detecting double D loop structure, group II nucleic acids) and each group requires a different search (see above). Regardless of the size of subject matter, if the inventions are independent or distinct and would be a serious burden on the examiner the restriction is proper.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 6 and 36-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking

claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 02/15/2006.

Claim Rejections - 35 USC § 112- Second Paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a). Claims 1-5 are indefinite. Claim 1 is drawn to a method for producing a stabilized double D loop at a target sequence within a double-stranded nucleic acid. However, the final process step is one of contacting the double-stranded nucleic acid with a first oligonucleotide and a second oligonucleotide. Accordingly, it is unclear as to whether the claim is intended to be limited to method of contacting a double stranded nucleic acid with a first and second oligonucleotide or for producing a stabilized double D loop at a target sequence within a double-stranded nucleic acid as referred to in the preamble. Applicants should amend the claim to indicate how the step of contacting a double stranded nucleic acid with a first and second oligonucleotide results in producing a stabilized double D loop at a target sequence within a double-stranded nucleic acid as recited in the preamble.

(b). Claims 7-11 are indefinite. Claim 7 is drawn to a method for detecting the presence of a desired target sequence within a double-stranded nucleic acid. However, the final process step is one of detecting stabilized double D loops having oligonucleotides. Accordingly, it is

unclear as to whether the claim is intended to be limited to method of detecting stabilized double D loops having oligonucleotides or for detecting the presence of a desired target sequence within a double-stranded nucleic acid as referred to in the preamble. Applicants should amend the claim to indicate how the step of detecting stabilized double D loops having oligonucleotides results in detecting the presence of a desired target sequence within a double-stranded nucleic acid.

(c). Claims 12-14 are indefinite. Claim 12 is drawn to a method for detecting the presence of a desired target sequence in a sample of double-stranded nucleic acids suspected of having sequences that differ at a target therein. However, the final process step is one of detecting stabilized double D loops, signaling the presence of a desired target sequence. Accordingly, it is unclear as to whether the claim is intended to be limited to method of detecting stabilized double D loops or for detecting the presence of a desired target sequence in a sample of double-stranded nucleic acids suspected of having sequences that differ at a target therein as referred to in the preamble. Applicants should amend the claim to indicate how the step of detecting stabilized double D loops results in detecting the presence of a desired target sequence in a sample of double-stranded nucleic acids suspected of having sequences that differ at a target therein.

(d). Claims 15-21 are indefinite. Claim 15 is drawn to a method for detecting in a sample of double stranded nucleic acids suspected of having sequences that differ at a target therein, the presence of at least two different target sequences. However, the final process step is one of discriminably detecting the species of first oligonucleotides present among stable D loops. Accordingly, it is unclear as to whether the claim is intended to be limited to method of detecting

the species of first oligonucleotides present among stable D loops or for detecting in a sample of double stranded nucleic acids suspected of having sequences that differ at a target therein, the presence of at least two different target sequences as referred to in the preamble. Applicants should amend the claim to indicate how the step of discriminably detecting the species of first oligonucleotides present among stable D loops results in detecting in a sample of double stranded nucleic acids suspected of having sequences that differ at a target therein, the presence of at least two different target sequences.

(e). Claims 27-32 are indefinite. Claim 27 is drawn to a method of protecting a restriction site target within double-stranded nucleic acids from cleavage during a restriction digest. However, the final process step is one of digesting said double-stranded nucleic acids with a restriction enzyme that recognizes said target sequence. Accordingly, it is unclear as to whether the claim is intended to be limited to method of digesting said double-stranded nucleic acids with a restriction enzyme that recognizes said target sequence or for protecting a restriction site target within double-stranded nucleic acids from cleavage during a restriction digest as referred to in the preamble. Applicants should amend the claim to indicate how the step of digesting said double-stranded nucleic acids with a restriction enzyme results in protecting a restriction site target within double-stranded nucleic acids from cleavage during a restriction digest.

(f). Claims 33-35 are indefinite. Claim 33 and 35 are drawn to a method of cleaving at or near a target sequence within a double-stranded nucleic acid. However, the final process step is one of reacting double-stranded nucleic acid with an enzyme that cleaves the double stranded nucleic acid. Accordingly, it is unclear as to whether the claim is intended to be limited to

method of reacting double-stranded nucleic acid with an enzyme that cleaves the double stranded nucleic acid or cleaving at or near a target sequence within a double-stranded nucleic acid as referred to in the preamble. Applicants should amend the claim to indicate how the step of reacting double-stranded nucleic acid with an enzyme that cleaves the double stranded nucleic acid results in cleaving at or near a target sequence within a double-stranded nucleic acid as referred to in the preamble.

(g). Claims 2, 8, 13, 23, and 28 recites the limitation "said second, recombinase-free oligonucleotide" in line 3 of the claims. There is insufficient antecedent basis for this limitation in the claim. Claims 2, 8, 13, 23, and 28 depend on claims 1, 7, 12, 22, and 27, respectively and claims 1, 7, 12, 22, and 27 do not recite a second oligonucleotide that is recombinase-free. Claims 1, 7, 12, 22, and 27 recite "second oligonucleotide is not substantially bound by a recombinase", however this recitation does not limit the second oligonucleotide to be recombinase-free and as such claims 2, 8, 13, 23, and 28 lack antecedence basis.

(h). The term "substantially" in claim 1, 7, 12, 15, 22, 27, 33, and 35 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear if "not substantially bound" means the second oligonucleotide is not bound to RecA, the second oligonucleotide is bound transiently to RecA, the second oligonucleotide is only bound to certain regions of RecA, RecA only bound to certain regions of the second oligonucleotide or is the second oligonucleotide affinity to RecA less than the affinity of the first oligonucleotide to RecA.

Claim Rejections - 35 USC § 112-Written Description

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 4 is drawn to a recombinase that is E. Coli RecA protein or mutein therof. The specification teaches discloses RecA protein refers to a family of Rec-A like recombination proteins having essentially all or most of the same functions, particularly: ability to position properly oligonucleotides on their homologous targets for subsequent extension by DNA polymerase, ability to topologically prepare duplex nucleic acid for DNA synthesis, and ability of RecA/oligonucleotide complexes efficiently to find and bind to complementary sequences (see page 13, lines 22-27). The specification asserts the best characterized RecA protein is E. Coli and many organisms have RecA-like strand transfer proteins (see page 13, lines 28-30 and page 14, lines 1-5). The specification asserts that RecA protein can be the mutant RecA-803 protein of E. coli (see page 14, lines 6-7).

While the specification does teach several different RecA-like strand transfer proteins and asserts a mutant RecA-803 protein, it does not however teach a representative number of

sequences of the large genus of RecA muteins, encompassed by the claims. The specification does not teach or describe the critical amino acids or regions of RecA that allow for biochemical and biological activity of RecA, particularly the ability of RecA to bind oligonucleotides and form double d-loop structures. The specification does not teach biochemical or biological functional studies that would allow the artisan to determine if a protein was within the scope of the claimed genus.

Since the specification has not taught or described critical structural features and activity assays that the skilled artisan could use to determine which proteins correspond to RecA muteins or a teaching of how to produce RecA muteins, the skilled artisan would have no way of knowing if any protein fell within the genus of the claimed RecA mutein because the specification does not provide a description of RecA muteins, particularly a protein that is functionally equivalent to RecA.

The instant claims are drawn to undisclosed sequences encoding modification that have not been contemplated. The specification provides insufficient written description to support the genus encompassed by the claim. Absent a written description, the specification fails to show that the applicant was "in possession of the claimed invention" at the time the application for the patent was filed. Further, the genus of polynucleotides comprised by the claim is a large variable genus, which can potentially encode proteins of diverse functions and read on genomic sequences. The specification only discloses a selected number of species of the genus RecA, Rec1, Rec2, Rad51, Rad51B, Rad51C, Rad51d, Rad51E, XRCC, DMC1 and RecA-803, which is insufficient to put one of ordinary skill in the art in possession of all attributes and features of all species within the genus. Thus one skilled in the art cannot reasonably conclude that

applicant had possession of the claimed invention at the time the instant application was filed with respect to claims 4.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116.)

With the exception of RecA, Rec1, Rec2, Rad51, Rad51B, Rad51C, Rad51d, Rad51E, XRCC, DMC1 and RecA-803, the skilled artisan cannot envision the detailed chemical structure of the encompassed proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993), and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. In *Fiddes v. Baird*, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In *re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it

obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 3-5, 7, 9-12, 14-22, 24-27, 29-35, are rejected under 35 U.S.C. 102(b) as being anticipated by Sena et al. (US Patent 5670316 Sept 1997). The phrase "is not substantially bind" is being interpreted to encompass that some RecA is bound to the second oligonucleotide.

With regard to claim 1, 4, 7, 12, 15, 18, and 22, Sena et al. teach a method of detection and isolating a linear duplex DNA (claim 18) having a first and second strands, containing a first internal DNA target sequence (see column 5, lines 55-57). Sena et al. teach a set of two DNA probes provided, having a first and second probe strands, where the first and second probe strand contain complementary sequence to the first and second target sequence strands and contain complementary overlap between the probe strands (see column 5, lines 55-60). Sena et al. teach the probes coated with RecA protein and combined with the linear duplex DNA which contains the target sequence under conditions that produce a probe: target complex containing the probe strands and both target strands which is stable to deproteinization (producing a stabilized double

D loop) (claim 1) (see column 5, lines 60-67). Sena et al. teach separating the mixture of nucleic acid molecules from the probe: target complex (detecting stabilized double D loop) (purifying double stranded nucleic acids) (see column 6, lines 2-7). Sena et al. teach the detection method can be applied to the detection of duplex DNA in any nucleic acid sample and further can be used in applications of clinical diagnosis of infection diseases to include diagnosis of certain genetic diseases caused by specific deletion/mutation, insertions, or rearrangements in mammalian DNA (see column 15, lines 24-26 and 29-30).

With regard to claim 3, 9-10, 14, 16, 17, 19, 25, 31 Sena et al. teach the use of methylated probes to detect target and form double d-loop complex (see column 22, lines 39-44). Sena et al. teach the use of ^{32}P- and biotin-labeled 121-mer probe strand (1st and 2nd oligonucleotide probe complementary to target sequence (see column 13, lines 50-53). Sena et al. teach direct labeling of probe strands with fluorescent moieties like fluorescien-11-dUTP (see column 21, lines 57-60). Sena et al. teach individual

With regard to claim 5, 11, 24, 32, Sena et al. teach deproteinization after RecA catalyzed homologous probe: target reaction for 15-20 min. at 37°C (see column 30, lines 36-42).

With regard to claim 27, 29-30, 33-35, Sena et al. teach forming double D loop structures to detect the presence of target DNA in a sample by introducing alterations at the target/double D loop complex which modify, in a detectably manner by restriction enzyme cleavage. Sena et al. teach a region in a target DNA is chosen as the double stranded probe sequence and the probe sequence is modified to contain an internal restriction site that is not present in the target DNA. Sena et al. teach that upon formation of double D loop structure the complexes are deproteinized and then captured on a solid support and digested with the restriction enzyme for which the site

has been introduced in the probe sequence. Sena et al. teach a second detection method in which the target DNA is unmethylated and the double stranded probe is methylated before RecA protein-coating. Sena et al. teach the double D-loop complex is formed, the complex is captured and deproteinized and the same is digested with DpnI which cleaves its recognition site only when the A residue on both strands is methylated (see column 22, lines 10-65).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claim 2, 8, 13, 23, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sena et al. (US Patent 5670316 Sept 1997) in view of Bryant et al. (PNAS 1985, vol. 82,pp. 297-301).

Sena et al. (US Patent 5670316) teach a method of detection and isolating a linear duplex DNA having a first and second strands, containing a first internal DNA target sequence (where duplex DNA analyte present in a mixture of nucleic acid molecules) (see column 5, lines 55-57). Sena et al. teach a set of two DNA probes provided, having a first and second probe strands, where the first and second probe strand contain complementary sequence to the first and second target sequence strands and contain complementary overlap between the probe strands (see column 5, lines 55-60). Sena et al. teach the probes coated with RecA protein and combined with the linear duplex DNA which contains the target sequence under conditions that produce a

probe: target complex containing the probe strands and both target strands which is stable to deproteinization (see column 5, lines 60-67). Sena et al. teach separating the mixture of nucleic acid molecules from the probe: target complex (see column 6, lines 2-7). Sena et al. teach the detection method can be applied to the detection of duplex DNA in any nucleic acid sample and further can be used in applications of clinical diagnosis of infection diseases to include diagnosis of certain genetic diseases caused by specific deletion/mutation, insertions, or rearrangements in mammalian DNA (see column 15, lines 24-26 and 29-30). Sena et al. does not teach a second oligonucleotide that is recombinase-free.

Bryant et al. teach a method of renaturation of complementary DNA strands by recA protein. Byrant et al. teach that higher levels of RecA protein markedly reduced the rate or renaturation (see page 298, 2nd full paragraph). Bryant et al. further teach renaturation reaction promoted by RecA protein proceeds optimally at levels of RecA protein sufficient to cover 10-15% of the DNA and RecA protein levels that are sufficient to approach saturation of the DNA strands produce a marked decrease in the efficiency of renaturation (see page 300, 1st full paragraph, 2nd column). Bryant et al. teach that similar conclusions were reached on the analysis of RecA protein-promoted D-loop formation (see page 300, 1st full paragraph, 2nd column).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the method of detection and isolating a linear duplex DNA using RecA coated probes to form a double D-loop complex by Sena et al. to include only the first probe coated with RecA and second probe without any RecA bound because saturation of DNA strands with RecA produce a marked decrease in the efficiency of hybridization as taught by Bryant. The ordinary artisan would have been motivated to improve the method of

coating both first and second probe with RecA as taught Sena et al. with the method of reducing the amount of RecA as taught by Bryant et al. because Bryant teaches that optimal levels of RecA for hybridization cover only 10-15% of the DNA and saturation levels of RecA coating DNA strands decrease the efficiency of renaturation. The ordinary artisan would have had a reasonable expectation of success that the use of coating only the first single stranded probe with RecA could be used in the method of Sena et al. because Bryant et al. teach that similar conclusions of less RecA mechanisms of binding were seen in d-loop formation.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-5, 7-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-67, 72-78 of copending Application No. 10/260150. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 1-5 and 7-26 are generic to all that is recited in claims 1-67, 72-78 of copending application no. 10/260150. Claims 1-2, 55-56, 63-34, 72, and 76 of '150 fall entirely in the scope of instant claims 1,7, 12, 15, 22 comprising a method producing a double d-loop and detecting the presence of a desired target sequence with

formation of a double d-loop with two oligonucleotides and the invention of instant claims 2-5, 8-11, 13-14, 16-21, and 23-26 are recited in dependent claims 3-49, 21-24, 32, 37-40, 47-48, and 61.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarae Bausch whose telephone number is (571) 272-2912. The examiner can normally be reached on M-F 10am-7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application

or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Sarae Bausch, PhD.
Examiner
Art Unit 1634

RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER